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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER

HARRIS, CARRIE R

ART UNIT	PAPER NUMBER
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3735

NOTIFICATION DATE	DELIVERY MODE
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11/13/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary

Application No.

10/586,646

Applicant(s)

VAN DER WEIDEN, ROBERTUS
MATTHEUS FELIX

Examiner

Carrie Harris

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-75, 91-103, 105-107, 110 and 111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-75, 91-103, 105-107, 110, and 111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>19 July 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to the Amendment filed 17 August 2009. The Examiner acknowledges the cancellation of claims 76-90, 104, 108, 109, 112, and 113. Claims 54-75, 91-103, 105-107, 110, and 111 are now pending.

Election/Restrictions

2. Applicant's election without traverse of Group I, claims 54-75, 91-103, 105-107, 110, and 111 in the reply filed on 17 August 2009 is acknowledged.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the laparoscope must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 40 and 160. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 15a, 15b, 15c, 50a, 50b, and V. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply

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to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

6. Claims 58 and 72 are objected to because of the following informalities: at line 2, "comprise" should read --comprises--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 54-75, 91-103, 105-107, 110, and 111** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 54, 62, 91, and 97, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 72, 91, and 97, the term "preferably" renders the claim indefinite because it is unclear whether the limitations following the term are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 72, 91, 95, and 97, the use of "and/or" in claim language renders the claim indefinite. It is unclear whether the limitation(s) preceding "and/or", the limitations following "and/or", or both are part of the claimed invention.

Claim 67 recites the limitation "the mat" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Regarding claims 54, 64, 91, and 97, Applicant asserts that the claim element "connection means" is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, it is unclear whether the claim element is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph, because it is not modified by sufficient structure for performing the claimed function. If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to:

(a) Amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines: the phrase "means for" or "step for" must be modified by functional language and the phrase must **not** be modified by sufficient structure, material, or acts for performing the claimed function; or

(b) Show that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or acts for performing the claimed

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function which would preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP § 2181.

Claim 98 is indefinite as it recites “the second tube” which is not positively required in claim 97, which recites the “second tube or rod”.

Claim 105 is indefinite as it recites “the second tube” which is not positively required in claim 54, which recites the “second tube or rod”.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claims 54, 59-68, 72, 91-103, 105, 107, 110, and 111** are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,954,057 (Li).

Regarding **claim 54**, Li teaches an assembly for use in the attachment of a patient's vaginal apex or uterus or rectum to her/his spine, comprising a first tube (*Figure 23, housing, 355*) having a length adapted to the distance from the outer wall of the patient's abdomen to the sacrum (Device is capable of extending from the outer wall of the patient's abdomen to the sacrum as that distance depends on the dimensions of the patient's anatomy; col. 16, line 40), which first tube (*housing, 355*) is provided with a distal end capable of being brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage (*Figure 23, passageway, 370*) from

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the distal to the proximal end thereof (col. 16, lines 41-43), a second tube (*Figure 23, shaft, 378*) having a length that at least equals the length of the first tube (*housing, 355*) (col. 16, lines 45-46), which second tube (*shaft, 378*) is provided with a distal end and comprises an opposite proximal end, at least one attachment means (*Figure 22, suspension strap, 315*) provided with a distal end (*Figure 9, aperture, 53* on *Figure 22, portion, 325*) for attachment to the sacrum and a proximal end (*Figure 22, triangular portion of strap adjacent portion, 320*) for attachment of an end of connection means (*Figure 22, portion, 320*) for connection to the patient's vaginal apex or uterus or rectum (col. 12, line 66-col. 13, line 4; col. 16, lines 4-10; col. 17, lines 33-37), wherein the distal end of the second tube (*shaft, 378*) and the proximal end (triangular portion of strap adjacent *portion, 320*) of the attachment means are formed for functional mutual engagement (see *Figure 23*), wherein the second tube (*shaft, 378*) can be movably accommodated in the first tube (*housing, 355*) (col. 16, lines 41-43 and lines 48-50).

Regarding **claim 59**, Li teaches that the distal end of the second tube (*Figure 23, shaft, 378*) is formed for fittingly, holding the proximal end (*Figure 22, triangular portion of strap adjacent portion, 320*) of the attachment means (*Figure 22, suspension strap, 315*) (col. 16, lines 50-62).

Regarding **claim 60**, Li teaches that the second tube (*Figure 23, shaft, 378*) has an internal cavity (*Figure 23, bore, 380*), which is at least formed at the distal end (col. 16, lines 50-51).

Regarding **claims 61-63**, Li teaches that the second tube (*Figure 23, shaft, 378*) extends into the first tube (*Figure 23, housing, 355*) and at least a part of the connection

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means (*Figure 22, portion, 320*) is attached to the attachment means (*Figure 22, strap, 315*) and situated within the first tube (*housing, 355*) between the first tube (*housing, 355*) and the second tube (*shaft, 378*), wherein the distal end of the second tube (*shaft, 378*) is narrowed for together with the first tube (*housing, 355*) forming an accommodation space for said part of the connection means (col. 16, lines 55-61; see *Figure 23*).

Regarding **claims 64-65**, Li teaches that the second tube (*Figure 23, shaft, 378*) has an internal cavity (*Figure 23, bore, 380*), which is at least formed at the distal end, and wherein the distal end of the second tube (*Figure 23, shaft, 378*) forms an accommodation space for the proximal end of the attachment means (*Figure 22, strap, 315*) and is provided with a passage to the side (*Figure 23, slot, 381*) (col. 16, 50-54), wherein an end portion of the said part of the connection means (*Figure 22, portion, 320*), extends through the passage (*slot, 381*) and is situated around the distal end of the second tube (*shaft, 378*) (The term “around” is interpreted to mean “near”; col. 16, line 50-63).

Regarding **claim 66**, Li teaches that the said part of the connection means (*Figure 22, portion, 320*) comprises a mat of material capable of enabling bodily tissue ingrowth (col. 16, lines 4-8).

Regarding **claim 67**, Li teaches that the mat (*Figure 22, portion, 320*) is capable of being shirred up around the second tube (*Figure 23, shaft, 378*) (col. 16, lines 4-8 and lines 50-63).

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Regarding **claim 68**, Li teaches that the attachment means (*Figure 22, strap, 315*) has a diameter that at least almost corresponds to the diameter of the first passage (*Figure 23, passageway, 370*) (see *Figure 23*).

Regarding **claim 72**, Li teaches that the connection means (*Figure 22, portion, 320*) comprises a mat of material capable of enabling bodily tissue ingrowth (col. 16, lines 4-8), which mat preferably can be attached to threads.

Regarding **claim 91**, Li teaches an assembly capable of use in the attachment of a patient's vaginal apex, uterus or rectum to her/his spine, comprising a first tube (*Figure 23, housing, 355*) having a length adapted to the distance from the outer wall of the patient's abdomen to the sacrum (Device is capable of extending from the outer wall of the patient's abdomen to the sacrum as that distance depends on the dimensions of the patient's anatomy; col. 16, line 40), which first tube (*housing, 355*) is provided with a distal end capable of being brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage (*Figure 23, passageway, 370*) from the distal to the proximal end thereof (col. 16, lines 41-43), a second tube (*Figure 23, shaft, 378*) having a length that at least equals the length of the first tube (*housing, 355*) (col. 16, lines 45-46), which second tube (*shaft, 378*) is provided with a distal end and comprises an opposite proximal end, at least one attachment means (*Figure 22, suspension strap, 315*) provided with a means for attachment (*Figure 9, aperture, 53* on *Figure 22, portion, 325*) to the sacrum and means for attachment (*Figure 22, triangular portion of strap adjacent portion, 320*) of connection means (*Figure 22, portion, 320*) (col. 12, line 66-col. 13, line 4; col. 16, lines 4-10; col. 17, lines 33-37), wherein the

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distal end of the second tube (*shaft*, 378) and the attachment means (*suspension strap*, 315) are formed for functional mutual engagement (see *Figure 23*), wherein the first passage (*passageway*, 370) is suitable for accommodation of the connection means (*portion*, 320) (see *Figure 23*).

Regarding **claim 92**, Li teaches that the first passage (*Figure 23, passageway*, 370) and the second tube (*Figure 23, shaft*, 378) are adapted to each other for fitting accommodation of the second tube (*shaft*, 378) (col. 16, lines 48-49).

Regarding **claim 93**, Li teaches that the connection means (*Figure 22, portion*, 320) are disposed between the first (*Figure 23, housing*, 355) and the second tube (*Figure 23, shaft*, 378) (see *Figure 23*).

Regarding **claim 94**, Li teaches the second tube (*Figure 23, shaft*, 378) forms a cavity (*Figure 23, slot*, 381) for accommodation of the connection means (*Figure 22, portion*, 320) (col. 16, lines 55-63; see *Figure 23*).

Regarding **claim 95**, Li teaches the connection means (*Figure 22, portion*, 320) comprises a mat of material capable of enabling bodily tissue ingrowth (col. 16, lines 4-8).

Regarding **claim 96**, Li teaches that the second tube (*Figure 23, shaft*, 378) forms a continuous cavity (*Figure 23, bore*, 380), from the proximal end to the distal end (col. 16, lines 50-51).

Regarding **claim 97**, Li teaches an assembly for use in surgery on a human body, comprising a first tube (*Figure 23, housing*, 355), provided with a distal end capable of being brought into engagement with a bone and comprising an opposite

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proximal end and having a first passage (*Figure 23, passageway, 370*) from the distal to the proximal end thereof (col. 16, lines 41-42), a second tube (*Figure 23, shaft, 378*) having a length that is at least equal to the length of the first tube, which second tube (*shaft, 378*) is provided with a distal end and comprises an opposite proximal end, at least one attachment means (*Figure 22, suspension strap, 315*) provided with a means for attachment (*Figure 9, aperture, 53 on Figure 22, portion, 325*) to the bone and means for attachment (*Figure 22, triangular portion of strap adjacent portion, 320*) of connection means (*Figure 22, portion, 320*) (col. 12, line 66-col. 13, line 4; col. 16, lines 4-10; col. 17, lines 33-37), wherein the distal end of the second tube (*shaft, 378*) and the attachment means (*suspension strap, 315*) are formed for functional mutual engagement (see *Figure 23*), wherein the first passage (*passageway, 370*) is suitable for accommodation of the connection means (*portion, 320*) (see *Figure 23*).

Regarding **claims 98 and 110**, Li teaches that the second tube (*Figure 23, shaft, 378*) forms a cavity (*Figure 23, bore, 380*) extending from the distal end to the proximal end (col. 16, lines 50-51).

Regarding **claims 99, 100, and 111**, Li teaches that the attachment means (*Figure 22, suspension strap, 315*) is directly connected to a connection mat (*Figure 22, portion, 320*) by hooking onto it (see *Figure 23*; connection mat and attachment means are integrally woven).

Regarding **claims 101 and 102**, Li teaches that the connection mat (*Figure 22, portion, 320*) is accommodated within the first tube (*Figure 23, housing, 355*) between

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the first tube (*housing*, 355) and the second tube (*Figure 23, shaft*, 378) (col. 16, lines 55-63).

Regarding **claim 103**, Li teaches that one or more threads that are connected to the attachment means (*Figure 22, suspension strap*, 315) extend through the cavity (*Figure 23, slot*, 381) out of the proximal end of the second tube (*Figure 23, shaft*, 378) (slot is in the proximal end of the second tube, col. 16, lines 55-62).

Regarding **claim 105**, Li teaches that the second tube (*Figure 23, shaft*, 378) can be snugly and movably accommodated in the first tube (*Figure 23, housing*, 355) (col. 16, lines 48-49).

Regarding **claim 107**, Li teaches that the distal end of the second tube (*Figure 23, shaft*, 378) is formed for fittingly, rotation-fixed holding the proximal end of the attachment means (*Figure 22, suspension strap*, 315) (see *Figure 23*).

11. **Claims 54-62, 64-66, 68, 71, 72, 74, 91-95, 97, 98, 103 and 105-107** are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.).

Regarding **claim 54**, Thierfelder et al. teaches an assembly for use in the attachment of a patient's vaginal apex or uterus or rectum to her/his spine, comprising a first tube (trocar, [0139]) having a length adapted to the distance from the outer wall of the patient's abdomen to the sacrum (Device is capable of extending from the outer wall of the patient's abdomen to the sacrum as that distance depends on the dimensions of the patient's anatomy), which first tube (trocar, [0139]) is provided with a distal end

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capable of being brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage from the distal to the proximal end thereof (trocar necessarily has a lumen; [0139]), a second rod (*Figure 11, surgical article, 40*) having a length that at least equals the length of the first tube ([0072]; trocar, [0139]), which second rod (*surgical article, 40*) is provided with a distal end and comprises an opposite proximal end ([0072]), at least one attachment means (*Figure 11, bone screw, 44*) provided with a distal end for attachment to the sacrum and a proximal end for attachment of an end of connection means (*Figure 11, suture, 43*) for connection to the patient's vaginal apex or uterus or rectum ([0072]-[0073]), such as one or more threads, wherein the distal end of the second rod (*surgical article, 40*) and the proximal end of the attachment means (*screw, 44*) are formed for functional mutual engagement ([0072]-[0073]; see *Figure 11*), wherein the second rod (*surgical article, 40*) can be movably accommodated in the first tube ([0072]-[0073]; trocar, [0139]).

Regarding **claim 55**, Thierfelder et al. teaches that the second rod (*Figure 11, surgical article, 40*) can be rotatably accommodated in the first tube ([0072]-[0073]; trocar, [0139]).

Regarding **claim 56**, Thierfelder et al. teaches that the attachment means (*Figure 11, bone screw, 44*) is a bone screw ([0072]-[0073]).

Regarding **claim 57**, Thierfelder et al. teaches that the proximal end of the second rod (*Figure 11, surgical article, 40*) is provided with means for rotation of the second rod (*surgical article, 40*) (surgical article has a motorized driver for rotating the shaft to implant the bone screw, [0072]-[0073]).

Regarding **claims 58 and 106**, Thierfelder et al. teaches that the rotation means comprises an arm that is transverse to the second rod (*Figure 11, surgical article, 40*), wherein the arm projects to both sides of the second rod (*surgical article, 40*) (motorized driver necessarily comprises an arm portion that is transverse to the shaft so that rotational energy is transferred to the shaft, [0072]-[0073]).

Regarding **claim 59**, Thierfelder et al. teaches that the distal end of the second rod (*Figure 11, surgical article, 40*) is formed for fittingly, holding the proximal end of the attachment means (*Figure 11, bone screw, 44*) ([0072]-[0073]; [0139]).

Regarding **claim 60**, Thierfelder et al. teaches that the second rod (*Figure 11, surgical article, 40*) has an internal cavity, which is at least formed at the distal end (second rod necessarily has an internal cavity for containing the suture, see *Figure 11*, [0072]-[0073]).

Regarding **claims 61 and 62**, Thierfelder et al. teaches that the second rod (*Figure 11, surgical article, 40*) extends into the first tube (trocar, [0139]) and at least a part of the connection means (*Figure 11, suture, 43*) is attached to the attachment means (*Figure 11, bone screw, 44*) and situated within the first tube ([0072]-[0073]; trocar, [0139]), wherein the said part of the connection means (*suture, 43*) is situated between the first (trocar, [0139]) and the second rod (*surgical article, 40*) ([0072]-[0073]; trocar, [0139]; see *Figure 11*).

Regarding **claim 64**, Thierfelder et al. teaches that the second rod (*Figure 11, surgical article, 40*) has an internal cavity, which is at least formed at the distal end, and wherein the distal end of the second rod (*surgical article, 40*) forms an accommodation

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space for the proximal end of the attachment means (*Figure 11, bone screw, 44*) and is provided with a passage to the side (see *Figure 11*), wherein an end portion of the said part of the connection means (*Figure 11, suture, 43*), such as a thread, extends through the passage (see *Figure 11*; [0072]-[0073]).

Regarding **claims 65 and 66**, Thierfelder et al. teaches that at least a part of the connection means (*Figure 11, suture, 43*) is attached to the attachment means (*Figure 11, bone screw, 44*) and is situated around the distal end of the second rod (*Figure 11, surgical article, 40*), and is capable of being wrapped or shirred up around the second rod (*surgical article, 40*) (see *Figure 11*; [0072]-[0073]; The term “around” is interpreted to mean “near”).

Regarding **claim 68**, Thierfelder et al. teaches that the attachment means (*Figure 11, bone screw, 44*) has a diameter that at least almost corresponds to the diameter of the first passage (trocar lumen, [0139]).

Regarding **claim 71**, Thierfelder et al. teaches that the first tube (trocar, [0139]) is provided with a handle near the proximal end (trocar necessarily has some portion near the proximal end where the surgeon grips the trocar to manipulate it properly, [0139]).

Regarding **claim 72**, Thierfelder et al. teaches that the connection means (*Figure 11, suture, 43*) comprises one or more threads that are attached to the attachment means (*Figure 11, bone screw, 44*) ([0072]).

Regarding **claim 74**, Thierfelder et al. teaches that the device is sterilely accommodated in hermetically closed packaging ([0067]).

Regarding **claim 91**, Thierfelder et al. teaches an assembly for use in the attachment of a patient's vaginal apex, uterus or rectum to her/his spine, comprising a first tube (trocar, [0139]) having a length adapted to the distance of the outer wall of the patient's abdomen to the sacrum (Device is capable of extending from the outer wall of the patient's abdomen to the sacrum as that distance depends on the dimensions of the patient's anatomy), which first tube (trocar, [0139]) is provided with a distal end capable of being brought into engagement with the sacrum and comprising an opposite proximal end and having a first passage from the distal to the proximal end thereof (trocar necessarily has a lumen; [0139]), a second rod (*Figure 11, surgical article, 40*) having a length that is at least equal to the length of the first tube, preferably larger, which second rod (*surgical article, 40*) is provided with a distal end and comprises an opposite proximal end ([0072]), at least one attachment means (*Figure 11, bone screw, 44*) that is provided with means for attachment to the sacrum and means for attachment of connection means (*Figure 11, suture, 43*), such as one or more threads, wherein the distal end of the second rod (*surgical article, 40*) and the attachment means (*bone screw, 44*) are formed for functional mutual engagement, wherein the first passage is suitable for accommodation of the connection means (*suture, 43*) (see *Figure 11*; [0072]-[0073]; [0139]).

Regarding **claim 92**, Thierfelder et al. teaches that the first passage and the second rod (*Figure 11, surgical article, 40*) are adapted to each other for fitting accommodation of the second rod (*surgical article, 40*) (trocar lumen, [0139]).

Regarding **claims 93-95**, Thierfelder et al. teaches that the connection means (*Figure 11, suture, 43*) are disposed between the first (trocar, [0139]) and the second rod (*Figure 11, surgical article, 40*), wherein the second rod (*surgical article, 40*) forms a cavity for accommodation of the connection means (*suture, 43*), and wherein the connection means (*suture, 43*) comprises threads capable of enabling bodily tissue ingrowth (see *Figure 11*; [0072]-[0073]; [0139]).

Regarding **claim 97**, Thierfelder et al. teaches an assembly for use in surgery on a human body, comprising a first tube (trocar, [0139]), provided with a distal end capable of being brought into engagement with a bone and comprising an opposite proximal end and having a first passage from the distal to the proximal end thereof (trocar necessarily has a lumen; [0139]), a second rod (*Figure 11, surgical article, 40*) having a length that is at least equal to the length of the first tube (trocar, [0139]; [0072]-[0073]), preferably larger, which second rod (*surgical article, 40*) is provided with a distal end and comprises an opposite proximal end ([0072]; [0073]), at least one attachment means (*Figure 11, bone screw, 44*) provided with means for attachment to the bone and means for attachment of connection means (*Figure 11, suture, 43*), such as one or more threads, wherein the distal end of the second rod (*surgical article, 40*) and the attachment means (*bone screw, 44*) are formed for functional mutual engagement, wherein the first passage is suitable for accommodation of the connection means (*suture, 43*) (see *Figure 11*; [0072]-[0073]; [0139]).

Regarding **claims 98 and 103**, Thierfelder et al. teaches that the second rod (*Figure 11, surgical article, 40*) forms a cavity extending from the distal end (see *Figure*

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11), wherein one or more threads (*Figure 11, suture, 43*) that are connected to the attachment means (*Figure 11, bone screw, 44*) extend through the cavity out of the proximal end of the second rod (*surgical article, 40*) (see *Figure 11*; [0072]-[0073]).

Regarding **claim 105**, Thierfelder et al. teaches that the second rod (*Figure 11, surgical article, 40*) can be snugly and movably accommodated in the first tube ([0072]; trocar, [0139]).

Regarding **claim 107**, Thierfelder et al. teaches that the distal end of the second rod (*Figure 11, surgical article, 40*) is formed for fittingly, rotation-fixed holding the proximal end of the attachment means (*Figure 11, bone screw, 44*) ([0072]; [0073]).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claim 69** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,954,057 (Li) in view of U.S. Patent Application Publication No. 2002/0143234 (LoVuolo).

Regarding **claim 69**, Li teaches all of the limitations of claim 54 above (see discussion for claim 54). Li does not teach that the assembly comprises gauge means.

However, LuVuolo teaches a device for suspending a bodily structure comprising a first tube (*Figure 2, cannula, 18*) that is provided with gauge means (*Figure 2, stripes,*

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44) related to the sliding of a second tube (*Figure 2, deploying rod, 28*) in the first tube (*cannula, 18*) corresponding to the attachment length of the distal end of the attachment means (*Figure 2, anchor toggle, 32*) (Depth calibration stripes indicate the insertion depth of the cannula, which allows the surgeon to accurately access when the cannula is in the appropriate location to then deploy the anchor using the deploying rod, [0047], [0048], [0057]. Therefore, the stripes are related to the insertion depth of the second tube and the length of the sutures attached to the anchor, which is directly related to the tension of the organ suspension). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the gauge means of LuVuolo on the second tube of Li, because depth indicia allow the surgeon to accurately access when the delivery mechanism is in the appropriate location to then deploy the anchoring device (LuVuolo, [0057]).

14. **Claim 69** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.) in view of U.S. Patent Application Publication No. 2002/0143234 (LoVuolo).

Regarding **claim 69**, Thierfelder et al. teaches all of the limitations of claim 54 above (see discussion for claim 54). Thierfelder et al. does not teach that the assembly comprises gauge means.

However, LuVuolo teaches a device for suspending a bodily structure comprising a first tube (*Figure 2, cannula, 18*) that is provided with gauge means (*Figure 2, stripes, 44*) related to the sliding of a second tube (*Figure 2, deploying rod, 28*) in the first tube

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(*cannula*, 18) corresponding to the attachment length of the distal end of the attachment means (*Figure 2, anchor toggle*, 32) (Depth calibration stripes indicate the insertion depth of the cannula, which allows the surgeon to accurately access when the cannula is in the appropriate location to then deploy the anchor using the deploying rod, [0047], [0048], [0057]. Therefore, the stripes are related to the insertion depth of the second tube and the length of the sutures attached to the anchor, which is directly related to the tension of the organ suspension). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the gauge means of LuVuolo on the second tube of Thierfelder et al., because depth indicia allow the surgeon to accurately access when the delivery mechanism is in the appropriate location to then deploy the anchoring device (LuVuolo, [0057]).

15. **Claims 70, 73, and 75** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,954,057 (Li) in view of U.S. Patent No. 5,458,606 (Worrich).

Regarding **claims 70, 73, and 75**, Li teaches all of the limitations of claim 54 above (see discussion for claim 54). Li does not teach that the distal end of the first tube is serrated, nor does Li teach the use of a laparoscope or viewing screen.

However, Worrich teaches a system for implanting a surgical tack in the sacrum to suspend a prolapsed pelvic organ that comprises a first tube having a serrated distal edge, a laparoscope, and a viewing screen that is functionally connected to the laparoscope. It would have been obvious to one of ordinary skill in the art at the time of

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the invention to provide the laparoscope and viewing screen of Wortrich in the assembly of Li, because the laparoscope and viewing screen allows the surgeon to observe the surgical cavity remotely reduce patient recovery time, pain, and trauma (Wortrich, col. 1, lines 16-21 and col. 3, lines 63-67). Furthermore, It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a serrated edge on the distal tip of the first tube of Li as taught by Wortrich, because the serrated edge provides better engagement with the surface in which the attachment mechanism is to be placed (Wortrich, col. 6, lines 32-37).

16. **Claims 70, 73, and 75** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0028980 (Thierfelder et al.) in view of U.S. Patent No. 5,458,606 (Wortrich).

Regarding **claims 70, 73, and 75**, Thierfelder et al. teaches all of the limitations of claim 54 above (see discussion for claim 54). Thierfelder et al. does not teach that the distal end of the first tube is serrated, nor does Thierfelder et al. teach the use of a laparoscope or viewing screen.

However, Wortrich teaches a system for implanting a surgical tack in the sacrum to suspend a prolapsed pelvic organ that comprises a first tube having a serrated distal edge, a laparoscope, and a viewing screen that is functionally connected to the laparoscope. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the laparoscope and viewing screen of Wortrich in the assembly of Thierfelder et al., because the laparoscope and viewing screen allows the surgeon to

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observe the surgical cavity remotely reduce patient recovery time, pain, and trauma (Wortrich, col. 1, lines 16-21 and col. 3, lines 63-67). Furthermore, It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a serrated edge on the distal tip of the first tube of Thierfelder et al. as taught by Wortrich, because the serrated edge provides better engagement with the surface in which the attachment mechanism is to be placed (Wortrich, col. 6, lines 32-37).

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Harris whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. H./
Examiner, Art Unit 3735